Report to CLIAC on 6/14/01 Blood Products Advisory Committee Session: CLIA Criteria for In Vitro Diagnostic Tests: Applicability of Waivers to HIV Rapid Tests

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FDA/CBER/OBRR

Overview of Session

- Historical overview of CLIA waivers
  - Joe Hackett, FDA/CDRH
- Overview of the FDA draft CLIA waiver guidance
  - Tom Hearn, CDC/PHPPO
- Public health strategic goals for HIV testing
  - Ida Onorato, CDC/NCHSTP
- Requirements for moderate complexity tests and HCFA experience with CLIA-waived tests in the laboratory
  - Judy Yost, HCFA

Overview of Session, cont.

- FDA perspectives on CLIA waiver of rapid HIV tests
  - Elliot Cowan, FDA/CBER
- Public comment
  - Approximately 10 presenters
- Presentation of questions to committee
- Committee discussion

Question 1

- Considering the known benefits and risks of rapid HIV testing, should FDA consider the possibility of removing all CLIA quality assurance oversight for such tests (*i.e.* waive simple and accurate HIV testing from CLIA) under its proposed criteria?
- Committee Vote:
  - Yes: 0
  - No: 15
  - Abstain: 2
  - Consumer representative: No
  - Industry representative: Yes

Question 2

- If not, what are the criteria that should be applied in making waiver decisions for these tests?
- Committee recommendation:
  - Should be some oversight for rapid HIV tests
  - Consider pre-analytic and post-analytic concerns

Question 3

- If rapid HIV tests are not waived, is it appropriate to pursue other approaches under CLIA (*e.g.* limited public health use) to promote wider access to rapid HIV testing?
- Committee Vote:
  - Yes: 17
  - No: 0
  - Abstain: 0
  - Consumer representative: Yes
  - Industry representative: Yes

Follow-up

- When substantive progress is made, we will update BPAC and CLIAC